Pharmacist-Led Medication Reconciliation Upon Discharge from the Orthopedic Surgery Department

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Main Information

Primary registry identifying number
LBCTR2023125487

Protocol number
LAU.SOP.ER1.14/Sep/2022

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
The clinical trial was submitted several times before its commencement, but the website was down.

Date of registration in national regulatory agency
14/09/2022

Primary sponsor
Lebanese American University

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
19/03/2024

Date of registration in national regulatory agency
14/09/2022

Public title
Pharmacist-Led Medication Reconciliation Upon Discharge from the Orthopedic Surgery Department

Acronym

Scientific title
Pharmacist-Led Medication Reconciliation Upon Discharge from the Orthopedic Surgery Department: An Interventional Randomized Controlled Trial

Acronym

Brief summary of the study: English

Medication reconciliation is a formal process of comparing the medications a patient is taking with the newly prescribed medications to avoid potential problems or discrepancies. Medication reconciliation should be done at every transition of care. The current practice at Lebanese hospitals' orthopedic surgery departments does not involve pharmacy services.
This study is an interventional, randomized, non-blinded, controlled trial conducted at the Lebanese American University Medical Center—Rizk Hospital. Participants were ≥ 18 years old and discharged from the orthopedic surgery unit with at least one discharge medication. Patients were randomized either to the intervention arm or to the control arm. In the intervention arm, a pharmacist is involved in the discharge process by completing medication reconciliation, providing patient counseling, and conducting telephone follow-up. However, in the control arm, they received the normal standard of care. All patients received a phone call from the primary investigator on day 30 post-discharge to record the endpoints. The primary outcome was to compare the number of unintended medication discrepancies. The secondary outcome consisted of the occurrence of adverse drug events, patient satisfaction, and a composite endpoint of unplanned physician contact, emergency room admission, and hospital readmission on day 30 post-discharge (and individual components of the composite endpoint).

Brief summary of the study: Arabic

.التوفيق بين الأدوية هو عملية رسمية لمقارنة الأدوية التي يتناولها المريض مع الأدوية الموصوفة حديثًا لتجنب المشاكل أو التناقضات المحتملة
ينبغي إجراء التوفيق بين الأدوية في كل مرحلة انتقالية للرعاية. الممارسة الحالية في أقسام جراحة العظام في المستشفيات اللبنانية لا تشمل
خدمات الصيدلة. نظرًا لأن الصيادلة هم خبراء الدواء، فإننا نعتقد أن التعليم التفصيلي الذي يقدمه الصيادلة للمرضى يمكن أن يساعد في تحديد
.المزيد من الأخطاء الدوائية، وبالتالي منع الأحداث الدوائية الضارة
الدراسة عبارة عن تجربة تدخلية عشوائية غير معماة، أجريت في المركز الطبي في الجامعة اللبنانية الأميركية - مستشفى رزق. كان عمر
عامًا وخرجوا من وحدة جراحة العظام باستخدام دواء خروج واحد على الأقل. تم اختيار المرضى بشكل عشوائي إما إلى ذراع18المشاركين ≤
التدخل حيث يشارك الصيدلي في عملية الخروج من خلال استكمال التوفيق الدوائي وتوفير استشارات المرضى والمتابعة الهاتفية أو ذراع التحكم
.حيث تلقوا المستوى الطبيعي من الرعاية
يومًا، سنقوم بإحصاء عدد التناقضات غير المقصودة التي تم تحديدها في كل فرع ومقارنتها من حيث الأهمية. سنقوم أيضًا بإجراء نقطة30وبعد
بعد الخروج30نهاية مركبة للاتصال غير المخطط له بالطبيب، والدخول إلى غرفة الطوارئ، وإعادة الدخول إلى المستشفى في اليوم
بعد الخروج من المستشفى وسيتم حساب30(والمكونات الفردية لنقطة النهاية المركبة). سيتم حساب حدوث الأحداث الدوائية الضارة في اليوم
. بعد الخروج من المستشفى30رضا المريض في اليوم

Health conditions/problem studied: Specify

Number of unintended medication discrepancies identified after patient discharge from the orthopedic department

Interventions: Specify

Involving a pharmacist in the discharge process from the orthopedic surgery department by performing medication reconciliation, patient counseling, and telephone follow-up in addition to the standard of care.

Key inclusion and exclusion criteria: Inclusion criteria

Subjects must meet all the inclusion criteria to participate in the study
•Informed Consent
•Adult (≥18 years)
•Discharged from orthopedic surgery unit with ≥ 1 discharge medication

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

95

Key inclusion and exclusion criteria: Exclusion criteria

Subjects meeting any of the exclusion criteria at baseline screening will be excluded
•Did not provide consent
•Previously enrolled in another study
•Being transferred to another hospital
•Being transferred to another unit within the hospital

Type of study

Interventional

Type of intervention

Quality improvement

Type of intervention: Specify type

N/A

Trial scope

Safety

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Active

Study phase

N/A

Study design: Purpose

Health services research

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class
n/a

Therapeutic indication
n/a

Therapeutic benefit
n/a

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention
None retained

Biospecimen description
n/a

Target sample size
200

Actual enrollment target size
178

Date of first enrollment: Type
Actual

Date of first enrollment: Date
19/10/2022

Date of study closure: Type
Actual

Date of study closure: Date
30/04/2023

Recruitment status

Recruitment status: Specify

Complete

Date of completion

30/04/2023

IPD sharing statement plan

No

IPD sharing statement description

n/a

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

No Sources

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Souad Diab	Beirut	Lebanon	70336597	souad.diab@lau.edu	Lebanese American University
Scientific	Elsy Ramia	Beirut	Lebanon	03167962	elsy.ramia@lau.edu.lb	Lebanese American University

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
LAU Medical Center - Rizk Hospital	Souad Diab	Pharmacist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	14/09/2022	Elsy Ramia	elsy.ramia@lau.edu.lb	03167962

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Medication reconciliation upon discharge from the orthopedic department	2-Propanol (T51.2)	Medication Reconciliation

Interventions

Intervention	Description	Keyword
Medication reconciliation and patient counseling before discharge	Incorporating pharmacists in the discharge process by completing medication reconciliation and providing patient counseling	Medication Reconciliation and Patient Counseling
Patient telephone follow up	Pharmacist telephone follow-up of the patient 3 days post-dischage	Follow-up

Primary Outcomes

Name	Time Points	Measure
Unintended medication discrepancies identified	Day 30 post-discharge	Number of unintended medication discrepancies identified

Key Secondary Outcomes

Name	Time Points	Measure
unplanned physician contact, Emergency Room admission, hospital readmission	Day 30 post-discharge	Composite endpoint of unplanned physician contact, Emergency Room admission, hospital readmission (and individual components of the composite endpoint)
Adverse Drug Events	Day 30 post-discharge	Number and type of adverse drug events
Patient Satisfaction	Day 30 post-discharge	HCAHPS survey

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files